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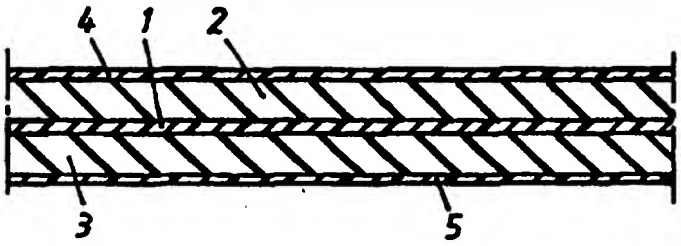
(54) Title: A HYPERTROPHIC SCAR DRESSING

(57) Abstract

The present invention relates to a hypertrophic scar dressing which includes silicone-gel on that side of the dressing which lies against the user's skin when worn. According to the invention a flexible carrier sheet (1) is embodied within the silicone-gel such that the gel forms continuous layers (2, 3) on both sides of the carrier material. The silicone-gel is tacky and skin-adherent and the dressing has a thickness of 0.2-1.5 mm.



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A HYPERTROPHIC SCAR DRESSING

The present invention relates to a dressing and then primarily but not exclusively to a hypertrophic scar dressing, said dressing including silicone gel on that side of the dressing which lies against the wearer's skin in use. Other areas of use are also conceivable, however, such as to cover typical operation scars or to cover particularly sensitive skin.

In normal wound-healing or sore-healing processes, the abundant vascular network is regenerated in the wound or the sore during the maturing phase and the collagen fibres collect in large bundles. Sometimes this maturing process fails to occur, so that granulation tissue remains beneath the covering epithelium for a relatively long period of time and may even develop and become enlarged. This is the clinical nature of a hypertrophic scar.

A hypertrophic scar is a raised, red and itching enlargement. The scar may be tender to the touch and to other external pressure and can form on every afflicted part of the body, although it is most prevalent after burn injuries and as a result of wounds across the breastbone and in the shoulder regions.

Hypertrophic scars often remain for a very long time, sometimes until the person concerned dies. In the case of adults, the hypertrophic scar will normally transform to a typical soft and pale scar after a year or so. In addition to itching and being relatively unsightly, hypertrophic scars in the region of joints can also impair joint mobility.

There is at present no quick and effective remedy for hypertrophic scars. The maturing phase can be accelerated in some instances, by injecting glucocorticoid into the scar formations.

It has been discovered in recent years that the regeneration rate of hypertrophic scars can be increased by applying silicone-gel plates to the scars. The mechanism by which the silicone-gel interacts with such scars has not been established, however. A number of products are available commercially for this purpose, for instance such products as Dow Corning Silastic Sheeting (Dow Corning), Cica-Care (Smith & Nephew), Epi-Derm (Biodermis), Nagosil (Nagor), among others. These products have the form of moulded silicone-gel plates having a thickness of 2-4 mm. In treating hypertrophic scars, these plates are placed over the scars and are worn for a relatively long period of time, often from three to twelve months, until the scars either have decreased or have regenerated.

The known silicone plates are relatively rigid and after having been placed over the scar have insufficient adhesion force to remain securely in position without some form of assistance. Consequently, it is necessary to secure the plates against the skin with the aid of a securing stocking, bandage, self-adhesive tape or some like means.

This makes the known silicone plates difficult to handle and to feel uncomfortable by the patients concerned. Since the patient needs to wear such plates continuously for a long period of time, due to the fact that scar regeneration is a slow process, optimization of patient comfort is of the greatest concern. A product which is difficult to handle and is felt to be uncomfortable can lower the patient's motivation to undergo the treatment.

An object of the present invention is to provide a hypertrophic scar dressing which is easy to handle, comfortable to wear and which will remain in position after having been applied, and which is also cheaper to manufacture than the aforesaid known dressings.

In accordance with the invention, this object is achieved with a dressing of the kind defined in the introduction which is characterized in that a flexible sheet of carrier material is enclosed in the silicone-gel such as to form a continuous gel layer on both sides of said carrier material; in that the silicone-gel is tacky and adhesive to skin; and in that the dressing has a thickness of 0.2-1.5 mm. There is thus provided a self-fixating dressing which can be easily applied and which is sufficiently flexible to conform to the contours of that part of the body to which it is secured and is thus comfortable to wear. Because the dressing is thin, it also has a high vapour permeability which further enhances wearer comfort. Furthermore, because the dressing is thin less silicone-gel is used than in the case of the known dressings and the cost of producing the inventive dressing is therefore much lower than the cost of producing the aforesaid known dressings.

According to one preferred embodiment of the invention, the dressing includes a liquid-impermeable top sheet on that side of the dressing which is distal from the wearer's skin in use, and the dressing has a thickness of 0.3-0.6 mm. The carrier material is permeable to liquid and the silicone-gel penetrates through the carrier material so that the layers of silicone-gel on respective sides of said carrier material will be in mutual contact, at least in punctiform contact. The carrier material has a thickness of 0.03-1 mm, preferably 0.05-0.1 mm, and a surface weight of 15-150 g/m^2, preferably 25-50 g/m^2, and is comprised either of nonwoven material, a knitted or woven textile material or of perforated plastic film. The silicone-gel has a penetration number or index P of 5-20 mm, preferably 7-14 mm, and the cohesion of the gel is greater than the adhesive strength of the gel on skin. The silicone-gel is preferably an addition-curing polydimethyl-siloxane gel. The top sheet is conveniently vapour permeable and is comprised of a polyurethane film having a thickness of less than 0.1 mm, preferably a thickness of about

0.025 mm. The dressing has a flexibility value H of less than 2.3 mm and the skin adhesion strength or force F1 of the dressing is 0.2-3 N, suitably 0.5-2 N and preferably 0.7-1.5 N. The dressing will suitably have a protective covering on that side thereof which is intended to lie against the wearer's skin in use, this protective covering being removed prior to applying the dressing.

The invention will now be described with reference to the accompanying drawings, in which

Fig. 1 is a schematic cross-sectional view of one embodiment of an inventive dressing;

Fig. 2 illustrates schematically a method of determining the adhesiveness of the dressing on skin;

Fig. 3 illustrates a measuring cone for use in a penetration test;

Fig. 4 illustrates schematically a penetration test for measuring softness; and

Fig. 5 illustrates schematically a method of measuring the flexibility of a dressing.

The embodiment of an inventive hypertrophic scar dressing illustrated in Figure 1 is comprised of a sheet of carrier material 1 which is coated on both sides thereof with a respective layer 2, 3 of soft, tacky silicone-gel which is self-adhesive and will adhere to skin. The dressing also includes a top sheet 4.

The silicone-gel contained in the dressing has two purposes. Firstly, as previously mentioned, the silicone-gel has a medical effect on hypertrophic scars. Secondly, the silicone-gel also functions as a means for securing the dressing to

the user's skin and to hold the dressing in place whilst worn. The adhesive strength of the silicone-gel has been adapted to this end, so that the adhesive strength will be sufficiently great to hold the dressing securely in place even when the dressing is subjected to the results of body movements and friction against the skin. However, the adhesive strength shall not be greater than the strength of the bonds with which outer skin cells bind to underlying cell layers. In relation to those adhesive compounds used conventionally in plasters and like devices for holding skin dressings in place, this optimization of the adhesive strength of the silicone-gel affords the advantage that very few skin cells will be stripped-off by the inventive dressing as the dressing is removed. When using conventional plasters or the like of the type Micropore® (3M), Mefix® (Mölnlycke), Hansaplast® (Beiersdorf) or Airstrip® (Smith & Nephew), a layer of dead skin cells will always accompany the adhesive compound each time a dressing is changed, until the stratum corneum is practically eliminated. Since hypertrophic scars require long treatment times with frequent dressing changes, there is a serious danger that the use of conventional adhesive compounds will lead to complications, such as pain among other things. The cohesion in the silicone-gel will preferably be greater than the strength with which the gel adheres to skin, so that the gel will not divide and leave residues on the skin as the dressing is removed.

Tacky, self-adhesive silicone-gels of the kind suitable for use in an inventive dressing are described in GB-A 2 192 142 and EP-A1 0 399 520.

The aforesaid optimization of the adhesive strength of the dressing requires the dressing to be highly flexible and pliable against the surface of the skin on which the dressing is applied. When a dressing is applied to an area of skin which is not fl-*, such as to a raised hypertrophic scar, stresses and tension will always occur in the dressing due

to its flexural resistance. The stiffer the dressing, the greater the residual stresses and tension therein. The skin adhering strength of the dressing according to the described embodiment is adapted so that essentially no skin cells will accompany the dressing as the dressing is removed, and is therewith slighter than the adhesive strength of conventional adhesive compounds. It is therefore important to ensure that after applying the dressing, the residual stresses are small, so as to reduce the risk of the dressing slowly loosening from the skin as a result of these stresses. For this reason, the described dressing is very flexible and pliable, which also enhances user comfort when the dressing is affixed to skin regions that bend or stretch as the body moves. To ensure effective dressing flexibility, the dressing will preferably have a thickness of less than 1.5 mm and preferably a thickness of less than 0.6 mm.

The carrier material 1 functions to reinforce the silicone-gel, which in itself has insufficient cohesion. This reinforcement increases the mechanical strength of the dressing and reduces the danger of the silicone-gel layer separating. For reasons mentioned above, the carrier material shall also be highly flexible and will only increase the stiffness of the composite dressing to a slight extent. The carrier material is comprised of a thin, continuous and coherent material. The carrier material is also preferably permeable to liquid, so that when impregnating the material silicone-gel will penetrate therethrough, at least in a punctiform fashion, so that respective silicone-gel layers 2, 3 on said carrier material will be joined together transversely through said material. The carrier material suitably has a thickness of 0.03-1 mm, preferably 0.1-0.2 mm, and a surface weight of 15-150 g/m^2, preferably 25-50 g/m^2.

Examples of carrier material are so-called nonwoven, knitted or woven textile material, perforated plastic film and the like.

The primary function of the top sheet 4 is to prevent the dressing from sticking to clothing or other objects that are liable to come into external contact with an applied dressing. The top sheet also contributes towards increasing the wear strength, tensile strength and tear strength of the dressing, and in the majority of cases it is beneficial when the top sheet has a small coefficient of friction against clothing or other materials with which the dressing can be expected to come into contact. The top sheet will preferably also have a high vapour permeability, so that moisture is able to pass from the skin and through the top sheet. The top sheet will also be highly flexible and will suitably comprise a liquid-impervious plastic film, preferably film that has a high vapour permeability. An example of suitable material in this regard is polyurethane having a thickness smaller than 0.1 mm, preferably a thickness of about 0.025 mm. The top sheet is advantageously secured to the gel layer 2 solely by virtue of the intrinsic adhesive force of the gel, so that the total stiffness of the dressing will not be increased or its vapour permeability decreased by the presence of an additional binder layer.

The layers 2, 3 of silicone-gel cover essentially the whole of the two mutually opposing surfaces of the carrier material and all the pores and cavities of the carrier material are filled with silicone-gel in the impregnating process. The combined thickness of the layers 2, 3 will suitably be equal to the thickness of the carrier material, and will preferably be twice as thick. The combined thickness of the two layers 2, 3 is suitably 0.3-0.6 mm. Such thin silicone-gel layers also have a relatively high vapour permeability.

The strength with which the dressing adheres to skin is measured in accordance with a method developed by the inventor, this method being shown schematically in Figure 2. Dressing strips · having a width of 25 mm are applied to the backs of eight subjects and allowed to remain in place for

four hours. The strips are then peeled off at a speed of 25 mm/s and the peeling force F1 measured. The strips shall be peeled off such that the angle defined between the lifted part of the strip A and the surface of the skin is 135°, i.e. the obtuse angle shown in Figure 2. In order to obtain a functional dressing, the force F1 shall have a mean value of 0.2-3 N. It has also been found that an extremely well-functioning dressing is obtained when the force F1 lies within the range of 0.5-2N, preferably 0.7-1.5 N.

The strength with which the dressing adheres to polished steel plates has also been measured with an 180° peel adhesion test according to ASTM-3330 M-81. In the case of a dressing having a total thickness of 0.45 mm and comprised of a polyurethane film top sheet, thickness 0.025 mm, a polypropylene nonwoven carrier material having a surface weight of 50 g/m², and a polydimethyl siloxane-gel, the adhesive strength or force F1 against steel was determined as being 0.7 N/25 mm in this test. The steel adhesion strength F1 measured in this way shall lie between 0.3-2.0 N, suitably between 0.5-1.5 N, preferably between 0.7-1.0 N.

Figures 3 and 4 illustrate a method of measuring the softness of a silicone-gel layer, by allowing a cone B weighing 62.5 g to penetrate down into a 30 mm thick silica-gel test body C under the force of gravity. The cone B used is shown in Figure 3 and has the following measurements: a = 65 mm, b = 30 mm, c = 15 mm and d = 8.5 mm. When measuring the softness of the gel, the cone B is first lowered to a position I, shown in broken lines in Figure 4, in which the cone apex just touches the surface of the gel body C. The cone B is then released so as to enable the cone to penetrate the sample C under the force of gravity. The number of millimeters through which the cone apex has penetrated into the sample body after 5 seconds is determined and the resultant distance constitutes the so-called penetration index P, which will, of course, be greater the softer the sample body.

Silicone-gels having penetration indexes of 5-20 mm, preferably 7-14 mm, have been found suitable for use in the inventive dressings.

The inventor has also developed a method of measuring flexibility, as illustrated in Figure 5. With this method, the short ends of a strip E measuring 25 x 100 mm are placed one on top of the other and the strip E is then placed carefully on a flat supportive surface. A loop of greater or smaller size, depending on the stiffness of the strip, will then be located at the end of the folded strip opposite the superimposed short ends thereof. A glide layer K, e.g. a thin paper sheet of well-defined thickness, is then placed on the loop. A plate G is then lowered slowly onto the loop and allowed to burden the loop with a force F2 of 0.15 N. The distance D between the highest part of the loop and the supportive surface is then measured. Twice the thickness of the strip E is then subtracted from the value D, in order to obtain a value H of the flexibility of the tape. The lower the value H, the greater the flexibility of the strip E. An inventive dressing shall have a flexibility value H of less than 2.3 mm, preferably less than 0.7 mm.

The flexibility of an inventive dressing was measured in accordance with the aforedescribed method. The dressing comprised a polyurethane top sheet, thickness 0.025 mm, applied on a soft addition-cured polydimethylsiloxane gel which was reinforced with a polypropylene nonwoven carrier material, thickness 0.15 mm, having a surface weight of 40 g/m^2. The dressing had a total thickness of 0.45 mm. The silicone-gel had a penetration number P of 10 mm and the skin adhesive strength F1 was 0.95 N. The flexibility value H was measured with the sample strip folded so as to cause the top sheet to face outwards, and also with the strip folded in the opposite direction, so that the gel layer faced outwards. The flexibility value H was 0 mm in both cases.

The flexibility of Dow Corning Silastic Gel Sheeting® having a thickness of 3.2 mm and including a top sheet was measured in a corresponding manner. With the strip folded so that the top sheet faced outwards, there was obtained a flexibility value H of 7.4 mm, whereas the flexibility value H obtained with the strip folded so that the gel layer faced outwards was 2.4 mm.

The aforedescribed dressing was provided conveniently in manufacture with a protective layer 5 for protecting the free self-adhesive silicone-gel surface of the dressing prior to use. The protective layer 5 may comprise plastic film or a multi-ply material, preferably a liquid impervious material. So as to facilitate removal of the protective layer when wishing to apply the dressing over a hypertrophic scar, the layer may comprise separated protective foils having overlapping edges, similar to the kind used with the majority of conventional plasters.

The described dressing can be sterilized by means of several conventional methods, such as steam sterilization, heat sterilization or sterilization with ethylene oxide.

Because, as earlier mentioned, the inventive dressing is sufficiently adhesive to ensure positive fixation and minimum self-release of the dressing at the same time as the adhesive strength of the dressing is sufficiently low to prevent pain and the removal of skin cells when the dressing is changed, the inventive dressing can also be used in circumstances other than covering hypertrophic scars, even though the dressing is intended primarily for this purpose. For instance, the dressing can be applied effectively to typical surgical scars both before and after removing the stitches, provided that no liquid leaks from the scar. The dressing can also be affixed to particularly sensitive skin, for instance to the skin of babies, to irradiated skin, or to the skin of patients who have been treated with skin-weakening medica-

ments, such as cortisone, for instance.

It will be understood that the described embodiments of the invention can be modified within the scope thereof. For instance, pharmaceutically active components can be admixed with the silicone-gel, which is particularly suitable vehicle for local anesthetics, for instance xylocaine-type anesthetics, and disinfectants or antibiotics. The top sheet may also be omitted in applications where there is no risk of contact with clothing or the like. It is also possible to use other materials for the top sheet, such as nonwoven, textile or paper materials. The use of liquid-impervious carrier materials is also conceivable when the adhesion of the gel to the carrier material shall be greater than its adhesion to the skin. The invention is therefore only restricted by the content of the following Claims.

CLAIMS

1. A dressing, particularly a hypertrophic scar dressing, which includes silicone-gel on that side of the dressing which lies against the user's skin when worn, characterized in that a flexible carrier sheet (1) is enclosed in the silicone-gel so that said gel will form continuous layers (2, 3) on both sides of the carrier material; in that the silicone-gel is tacky and skin adherent; and in that the dressing has a thickness of 0.2-1.5 mm.

2. A dressing according to Claim 1, characterized in that the dressing includes a liquid-impervious top sheet (4) on that side of the dressing which is distal from the wearer's skin in use.

3. A dressing according to Claim 1 or Claim 2, characterized in that the dressing has a thickness of 0.3-0.6 mm.

4. A dressing according to any one of Claims 1-3, characterized in that the carrier material (1) is liquid-impermeable; and in that the silicone-gel has penetrated through the carrier material such as to unite the silicone-gel layers (2, 3) on mutually opposite sides of the carrier material, at least in a punctiform fashion.

5. A dressing according to Claim 4, characterized in that the carrier material (1) has a thickness of 0.03-1 mm, preferably 0.1-0.2 mm, and a surface weight of 15-150 g/m^2, preferably 25-50 g/m^2.

6. A dressing according to Claim 5, characterized in that the carrier material (1) is comprised of either nonwoven material, a knitted or woven textile material, or perforated plastic film.

7. A dressing according to any one of Claims 1-5, characterized in that the silicone-gel has a penetration number P of 5-20 mm, preferably 7-14 mm.

8. A dressing according to Claim 7, characterized in that the cohesion of the gel is greater than the adhesive strength of the gel against skin.

9. A dressing according to Claim 7 or Claim 8, characterized in that the silicone-gel is an addition-curing polydimethylsiloxane gel.

10. A dressing according to any one of Claims 2-9, characterized in that the top sheet (4) is vapour-permeable.

11. A dressing according to Claim 10, characterized in that the top sheet (4) is comprised of polyurethane film having a thickness of less than 0.1 mm, preferably a thickness of about 0.025 mm.

12. A dressing according to any one of the preceding Claims, characterized in that the dressing has a flexibility value H of less than 2.3 mm.

13. A dressing according to any one of the preceding Claims, characterized in that the skin adhering strength F1 of the dressing is 0.2-3 N, suitably 0.5-2 N, preferably 0.7-1.5 N.

14. A dressing according to any one of the preceding Claims, characterized in that the dressing is provided with a protective covering (5) on that side of the dressing which is intended to lie against the wearer's skin in use, this protective covering being removed prior to applying the dressing.

Fig. 1

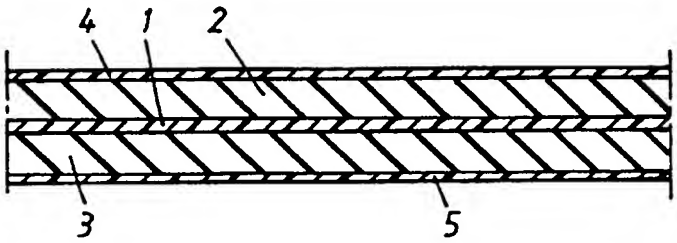


Fig. 2

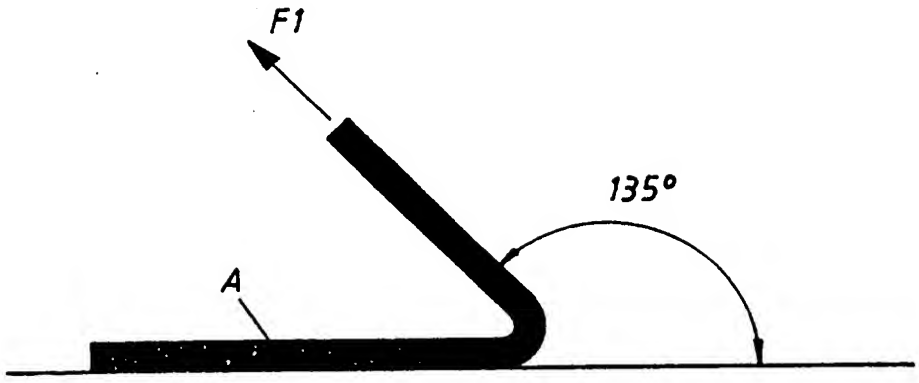
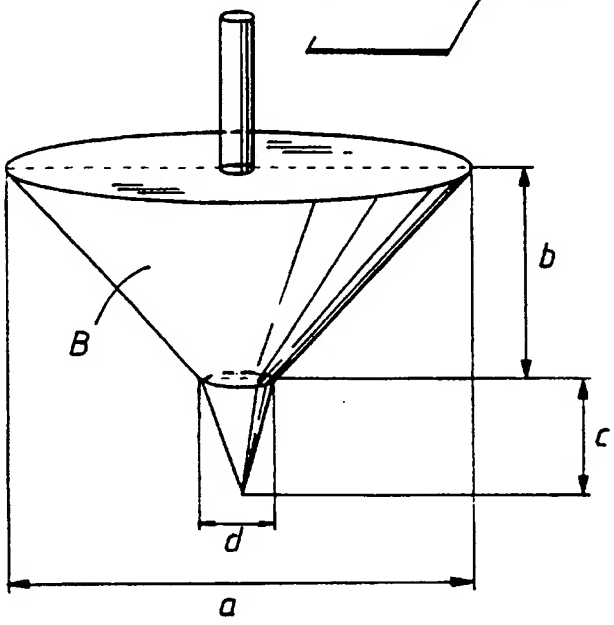


Fig. 3



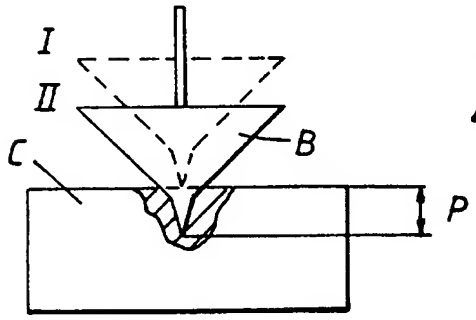
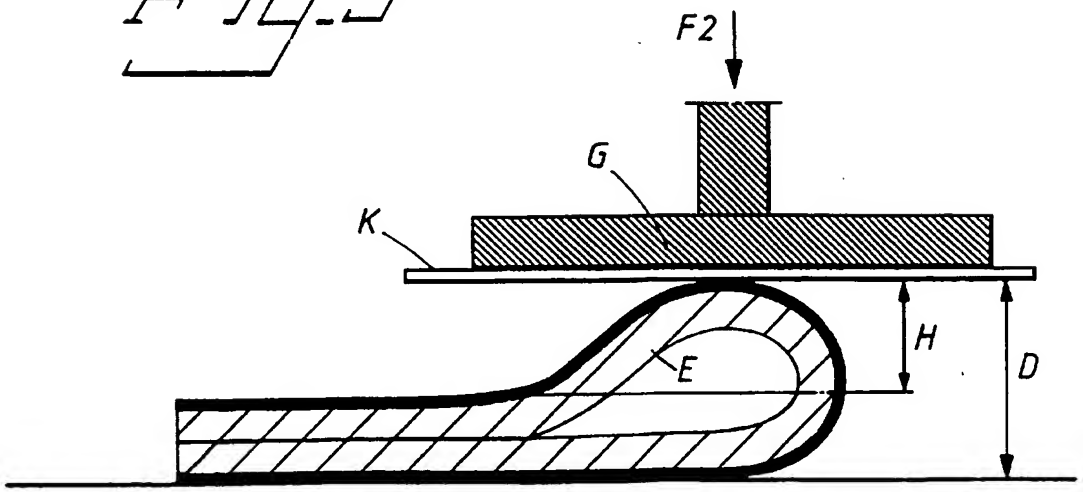


Fig. 4

Fig. 5



INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 95/01062

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61L 15/26, A61L 15/42, A61F 13/00
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61L, A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WPI, CLAIMS, CA, EPODOC

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 9319710 A1 (MÖLNLYCKE AB), 14 October 1993 (14.10.93) --	1-14
A	EP 0300620 A1 (DOW CORNING FRANCE S.A.), 25 January 1989 (25.01.89) --	1-14
A	EP 0251810 A2 (JOHNSON & JOHNSON), 7 January 1988 (07.01.88) -- --------	1-14

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
20 December 1995	10 -01- 1996
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INTERNATIONAL SEARCH REPORT

Information on patent family members

11/12/95

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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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		AU-B,B- 606436	07/02/91
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		CA-A- 1326191	18/01/94
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(12) # EUROPEAN PATENT SPECIFICATION

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Description

This invention relates to a medical or surgical dressing suitable for use in the treatment of burns and other injury.

The treatment of severe burns involves several phases. During the healing process management of the wound involves removing exudates and providing a sterile environment in which the formation of new skin cover can take place. Various forms of dressing for assisting in such management have been proposed. For example U.S. Patent 3 648 692 discloses a medical-surgical dressing for topical application to burns and the like which comprises a facing layer of neutral thrombogenic reticulated open cell material and a mutually secured co-extensive, gas-permeable microporous backing.

U.S. Patent No. 3 800 792 discloses a surgical dressing that is particularly useful for the treatment of burn wounds and which is made from a layer of collagen compressed foam film to which has been laminated a thin continuous layer of an inert polymer material such as polyurethane.

U.S. Patent No. 3 949 742 discloses a medical dressing which is adapted to perform as a synthetic skin for the therapy and protection of skin wounds, such as burns. The dressing comprises a unitary composite of a thin layer of thrombogenic reticulated foam cohesively secured to a thin elastomeric backing preferably of segmented polyurethane resin.

A further phase in burn therapy involves management of the burn scar. This is aimed at preventing scars from interfering with joint movement and other functions, and with reducing the cosmetic damage resulting from the scarring. A widely employed method of treating such scarring has been the use of pressure dressings. However, that method is less than satisfactory when the area to be treated is in a depression or in proximity to a joint. Another method has been described in the journal Burns, 9, pages 201 - 204 and involves the application of a silicone gel. Such a gel adapts itself readily to the contours of the human body and is indicated as an effective aid in the management of hypertrophic scarring.

By their nature silicone gels are difficult to handle. They are soft and frangible and the gel sheets are thus easily torn in use. It has been proposed to improve the strength and ease of handling of silicone gel sheets by embedding therein during manufacture a support material such as a net of polyester or other fibres. Although this technique has resulted in an improvement in the ability to handle and apply the gel sheet it has been found that the sheet still has a tendency to fragment during application and in use.

According to the present invention there is provided a surgical dressing comprising a sheet of silicone gel having a wound facing surface characterised in that said sheet has laminated to the other surface a film of silicone elastomer and the silicone gel and the silicone elastomer are both derived from compositions based on an alkenyl-substituted polydimethylsiloxane, an organosiloxane having silicon-bonded hydrogen atoms and a compound or complex of a platinum metal.

The sheet of silicone gel which forms one component of the dressing of this invention may be of any desired size. Depending on the area to be covered it may vary from a few to hundreds of square centimetres in area. The thickness of the gel layer is not critical but it should not be so thick that it will not conform substantially to the contours of the area to be covered. For general application a gel sheet having a thickness of from about 1mm to about 6mm is preferred. The silicone gel-forming compositions employed in the fabrication of the gel sheets are well known and have previously been employed in the production of surgical prostheses and in the encapsulation of electronic components. They can be described as soft, tacky, non-friable gels and are those obtained by the reaction of a polydimethylsiloxane having silicon-bonded alkenyl groups e.g. vinyl, allyl or hexenyl groups, an organosiloxane containing silicon-bonded hydrogen atoms and a catalyst for the reaction of SiH groups and silicon-bonded alkenyl groups, such catalysts being the platinum metals or compounds or complexes thereof. The consistency of the gel is determined by the ratio of reactive groups in the SiH-containing crosslinking agent to those in the polydimethylsiloxane. Compositions of this type may contain a small proportion of free polydiorganosiloxane fluid resulting from incomplete reaction of the alkenyl-substituted polydimethylsiloxane or from the incorporation of a non-reactive siloxane e.g. a liquid polydimethylsiloxane. They can be prepared according to the disclosures in, for example G.B. Patents 849 885, 945 580 and U.S. Patent 3 020 260. Such compositions cure at normal ambient temperatures. If desired, however, curing can be expedited by exposure to elevated temperatures, e.g. from about 40 °C to about 120 °C.

The silicone elastomer film which is laminated to the silicone gel sheet preferably has a thickness of from about 0.01cm to about 0.1cm. Thinner films can be employed but are more difficult to fabricate. Films of thickness up to about 0.2cm are also operative but such thicker films reduce the ability of the gel sheet to conform to the body contour and offer no compensating advantage. To obtain the maximum advantage from the presence of the film of silicone elastomer it should be at least substantially co-extensive with the gel sheet. If desired the edges of the film may extend beyond

the periphery of the gel sheet thus providing an area to which an adhesive may be applied for adhering the dressing to the body.

The silicone elastomer film is fabricated from an elastomer-forming composition based on an alkenyl-, e.g. vinyl-, substituted polydimethylsiloxane, an organosiloxane having silicon-bonded hydrogen atoms and a compound or complex of a platinum metal. Compositions of this type can be prepared in flowable form, they adhere to the silicone gel surface and can be cured at relatively low temperatures e.g. from about 30 °C to about 90 °C. They are especially suitable for use according to the fabrication technique hereinafter described employing a tray or similar shallow container. In addition to the polydiorganosiloxane and crosslinking components mentioned above the elastomer-forming composition may contain other ingredients such as fillers, pigments, low temperature cure inhibitors and additives for improving adhesion to the gel surface.

According to one method of making the dressing of this invention the gel sheet and the silicone elastomer film may be preformed by known procedures e.g. by moulding, calendering or casting and thereafter brought together. For example, the gel sheet may be preformed by casting and curing the gel-forming composition on a suitable substrate. The elastomer film may be preformed by calendering and the cured film applied over the gel sheet. Alternatively, the procedure may be reversed and the elastomer film applied first to the substrate. If necessary an adhesive may be employed to hold the components together in the laminated configuration.

Another method of making the dressings of this invention comprises (1) applying to a substrate a first composition which is the silicone gel-forming composition or is the silicone elastomer-forming composition, (2) curing the applied composition, (3) applying to the exposed surface of the cured first composition a layer of a second composition which is the silicone elastomer-forming composition or the silicone gel-forming composition respectively and (4) curing the second composition, whereby there is obtained a laminate of a silicone gel and a silicone elastomer.

In the performance of said method of this invention either the gel layer or the elastomer layer may be formed first. Thus, the first composition may be the gel-forming composition and the elastomer-forming composition is then applied as the second composition to the exposed surface of the cured gel. Alternatively, the elastomer-forming composition may be applied to the substrate as the first composition, the gel-forming composition being thereafter applied over the cured elastomer. If desired the formation of the elastomer film on the substrate may be facilitated by applying the elastomer-forming composition as a dispersion or solution in a volatile organic solvent or other carrier and thereafter removing the carrier by evaporation.

The substrate employed in step (1) of the process can be any surface which will impart to the applied compositions the desired sheet configuration. Thus, it may be a continuous belt on to which the gel-forming or elastomer-forming composition is spread. Depending on the consistency of the compositions the substrate may have barriers at its edges to restrict the flow of the compositions until cure takes place. A more preferred form of substrate, however, is a non-porous shallow container for example a tray of plastic into which the first composition is poured to a depth corresponding respectively to the desired thickness of the gel sheet or elastomeric film. The applied composition is then cured and the second composition applied to the required depth over the exposed surface of the cured first composition. Following the cure of the second composition the resulting composite, that is the gel sheet with its backing film of silicone elastomer may be removed and packaged. More conveniently, however, the composite is allowed to remain in the shallow container until ready for use. Such an arrangement is depicted in section in the drawing wherein the gel sheet 2 has on its exposed surface a film of silicone elastomer 3. The composite dressing is contained in a shallow tray 1 from which it is removed when required for use.

The container and contents may be sterilised if necessary and enclosed in a suitable sterile envelope or other external package ready for supply and use. It will thus be appreciated that the fabrication of the gel dressing in a tray or similar shallow container, as described hereinabove, has the significant advantage of minimising the handling of the dressing during manufacture, packaging and application.

When it is desired to carry out the manufacture of the dressings of this invention as a continuous process it is generally preferred to preform the cured, silicone elastomer film as a separate operation, for example by calendering or extrusion. The preformed film is then brought into contact with the silicone gel-forming composition which is thereafter cured. Thus, for example, the cured film may be laid on the exposed surface of the gel-forming composition supported on a suitable substrate, or, alternatively the gel-forming composition may be coated on to the preformed elastomer film. Cure of the gel-forming composition is then carried out, preferably by exposure to elevated temperatures.

The surgical dressings of this invention are particularly adapted for the treatment of hypertrophic scars during burn therapy. They may also find application in earlier phases of the treatment of

burns and in the treatment of wounds generally. If desired the dressings of this invention may contain or may be employed in conjunction with pharmaceutically-active substances, for example antiseptics, antibacterial agents, antifungal agents or other adjuvants employed in burn and wound treatment. Such adjuvants may be retained within the dressing or may be released during contact with the wound. Of special interest among such other adjuvants are growth factors, that is substances for increasing the rate of growth of new skin.

The following Examples illustrate the invention.

Example 1

A silicone elastomer-forming composition was prepared based on a mixture of a vinyl-substituted polydimethylsiloxane, a polymethylhydrogensiloxane, a reinforcing silica filler and a complex of chloroplatinic acid and a vinyl siloxane as catalyst. The composition was mixed with an equal weight of trichloroethane and the resulting 50% dispersion poured into a flat rectangular plastic tray of dimensions 150mm x 120mm x 5mm to a depth of 0.25mm. The tray was placed in an oven at 50°C for 20 minutes to evaporate the solvent and then heated to 80°C for one hour to cure the elastomer. The tray and contents were allowed to cool and there was then poured on to the exposed surface of the cured elastomer, to a thickness of 4mm, a flowable silicone gel-forming composition based on a similar platinum-catalysed cure system as the elastomer except that it contained no filler and the relative proportions of the vinyl groups and SiH groups were such as to provide a soft, tacky gel after cure. The tray and contents were placed in an oven at 90°C for 20 minutes to cure the applied gel-forming composition.

When cool the tray and contents were packaged in a sealable paper pouch and sterilised by exposure to ethylene oxide.

Example 2

A flowable, silicone elastomer-forming composition was prepared by mixing a vinyl-substituted polydimethylsiloxane, a polymethylhydrogen-siloxane, a reinforcing silica filler and a complex of chloroplatinic acid and a vinyl siloxane as catalyst. The composition was then coated on to a sheet of polyester film and its exposed surface covered with a second polyester film. The composite was passed between the rolls of calender and then exposed to a temperature of about 90°C to effect cure of the elastomer. Upon cooling and removal of the polyester film there was obtained a silicone elastomer film having a thickness of 0.018cm.

A portion of the film prepared as above was placed flat on the exposed surface of a layer of silicone, gel-forming composition of the type described in Example 1. The layer had a thickness of approximately 4mm and was contained in a shallow plastic tray of dimensions 150mm x 120mm x 5mm. The tray and contents were then placed in an oven at 90°C for 20 minutes to effect cure of the gel-forming composition. On cooling and removal from the tray the silicone elastomer film was found to be bonded firmly to the silicone gel layer.

Claims

1. A surgical dressing comprising a sheet of silicone gel having a wound-facing surface characterised in that said sheet has laminated to the other surface a film of silicone elastomer and the silicone gel and the silicone elastomer are both derived from compositions based on an alkenyl-substituted polydimethylsiloxane, an organosiloxane having silicon-bonded hydrogen atoms and a compound or complex of a platinum metal.

2. A dressing as claimed in Claim 1 characterised in that it includes an antiseptic, antibacterial agent, antifungal agent or other substance employed in the treatment of wounds and burns.

3. A dressing as claimed in Claim 2 characterised in that said other substance is a growth factor.

4. A process for making a surgical dressing characterised in that it comprises forming a cured silicone gel sheet and a cured silicone elastomer film and thereafter laminating said film with said sheet, and wherein said silicone gel and said silicone elastomer are as defined in Claim 1.

5. A process for making a surgical dressing characterised in that it comprises (1) applying to a substrate a first composition which is a silicone gel-forming composition or is a silicone elastomer-forming composition, (2) curing the applied composition, (3) applying to the exposed surface of the cured first composition a layer of a second composition which is a silicone elastomer-forming composition or a silicone gel-forming composition respectively and (4) curing the second composition, whereby there is obtained a laminate of a silicone gel and a silicone elastomer, and wherein said silicone gel-forming composition and said silicone elastomer-forming compositions are as defined in Claim 1.

6. A process as claimed in Claim 5 characterised in that the substrate is a tray or similar shallow container.

7. A process for making a surgical dressing characterised in that it comprises contacting a cured, silicone elastomer film with a silicone gel-forming composition, thereafter curing the silicone gel-forming composition in contact with the silicone elastomer film whereby there is obtained a laminate of a silicone gel and a silicone elastomer, and wherein said silicone elastomer and said silicone gel-forming composition are as defined in Claim 1.

8. A process as claimed in any one of Claims 4 to 7 characterised by the further steps of subjecting the laminate of silicone gel and silicone elastomer to sterilisation and packaging.

Revendications

1. Pansement chirurgical comprenant une feuille de gel silicone présentant une face de contact avec la plaie caractérisé en ce que ladite feuille comporte, stratifiée sur son autre face, une pellicule d'élastomère silicone et en ce que le gel silicone et l'élastomère silicone sont tous deux dérivés de compositions basées sur un siloxane de polydiméthyle à substitution d'alcényle, un organosiloxane présentant des atomes d'hydrogène à liaison silicone et un composé ou un complexe de platine métallique.

2. Pansement selon la revendication 1 caractérisé en ce qu'il contient un agent antiseptique, antibactérien, un agent antifongique ou une autre substance utilisée dans le traitement des plaies et brûlures.

3. Pansement selon la revendication 2 caractérisé en ce que ladite autre substance est un facteur de croissance.

4. Procédé de fabrication d'un pansement chirurgical caractérisé en ce qu'il englobe la formation d'une feuille de gel silicone durcie et d'une pellicule d'élastomère silicone durcie ainsi que la stratification ultérieure de ladite pellicule avec ladite feuille, ledit gel silicone et ledit élastomère silicone étant ainsi conformes à la définition donnée en revendication 1.

5. Procédé de fabrication d'un pansement chirurgical caractérisé en ce qu'il englobe (1) l'application sur un substrat d'une première composition qui est formatrice de gel silicone ou formatrice d'élastomère silicone, (2) le durcissement de la composition appliquée, (3) l'application sur la face exposée de première composition durcie d'une couche de seconde composition respectivement formatrice d'élastomère silicone ou formatrice de gel silicone et (4) le durcissement de la seconde composition, permettant ainsi d'obtenir un stratifié d'un gel silicone et d'un élastomère silicone, où ladite composition formatrice de gel silicone et lesdites compositions formatrices d'élastomère silicone sont conformes à la définition donnée en revendication 1.

6. Procédé selon la revendication 5 caractérisé en ce que le substrat est un plateau ou un conteneur semblable peu profond.

7. Procédé de fabrication d'un pansement chirurgical caractérisé en ce qu'il englobe la mise en contact d'une pellicule d'élastomère silicone durcie avec une composition formatrice de gel silicone, le durcissement ultérieur de la composition formatrice de gel silicone en contact avec la pellicule d'élastomère silicone, permettant ainsi d'obtenir un stratifié d'un gel silicone et d'un élastomère silicone, où ladite composition formatrice de gel silicone et ladite composition formatrice d'élastomère silicone sont conformes à la définition donnée en revendication 1.

8. Procédé selon l'une quelconque des revendications 4 à 7 caractérisé par les étapes supplémentaires de stérilisation et de conditionnement du stratifié de gel silicone et d'élastomère silicone.

Patentansprüche

1. Wundverband mit einer Silicongelschicht, deren eine Oberfläche der Wunde zugekehrt ist, dadurch gekennzeichnet, daß an die andere Oberfläche der Silicongelschicht ein Siliconelastomerfilm gebunden ist, wobei sowohl das Silicongel als auch das Siliconelastomer auf Massen auf Basis eines alkenylsubstituierten Polydimethylsiloxans, eines Organosiloxans mit siliciumgebundenen Wasserstoffatomen und einer Verbindung oder eines Komplexes eines Platinmetalls beruhen.

2. Wundverband nach Anspruch 1, dadurch gekennzeichnet, daß er ein Antiseptikum, ein antibakterielles Mittel, ein antifugales Mittel oder eine für die Behandlung von Wunden und Verbrennungen übliche sonstige Substanz enthält.

3. Wundverband nach Anspruch 2, dadurch ge-

kennzeichnet, daß die sonstige Substanz ein Wachstumsfaktor ist.

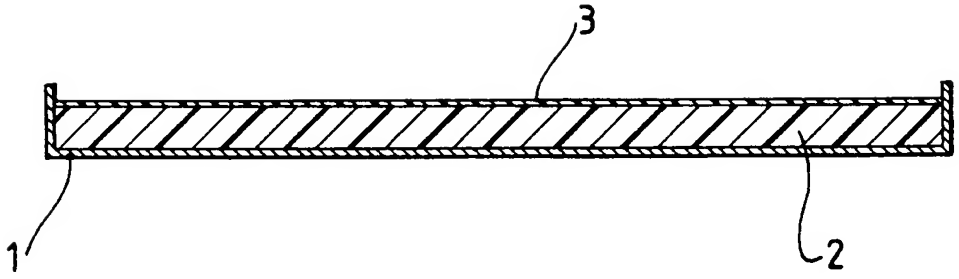
4. Verfahren zur Herstellung eines Wundverbands, dadurch gekennzeichnet, daß eine gehärtete Silicongelschicht und ein gehärteter Siliconelastomerfilm gebildet werden, und daß dieser Film dann mit der Schicht verbunden wird, wobei das Silicongel und das Siliconelastomer wie im Anspruch 1 definiert sind.

5. Verfahren zur Herstellung eines Wundverbands, dadurch gekennzeichnet, daß (1) auf einen Träger eine erste Masse aufgebracht wird, die eine ein Silicongel bildende Masse oder eine ein Siliconelastomer bildende Masse ist, (2) die aufgebrachte Masse gehärtet wird, (3) auf die freie Oberfläche der gehärteten ersten Masse eine Schicht aus einer zweiten Masse aufgebracht wird, bei der es sich um eine ein Siliconelastomer bildende Masse oder eine ein Silicongel bildende Masse handelt, und (4) die zweite Masse gehärtet wird, wodurch sich ein Schichtstoff aus einem Silicongel und einem Siliconelastomer ergibt, wobei als Masse zur Bildung des Silicongels und als Masse zur Bildung des Siliconelastomers Massen verwendet werden, wie sie im Anspruch 1 definiert sind.

6. Verfahren nach Anspruch 5, dadurch gekennzeichnet, daß der Träger ein Tablett oder ein ähnliches flaches Behältnis ist.

7. Verfahren zur Herstellung eines Wundverbands, dadurch gekennzeichnet, daß ein gehärteter Siliconelastomerfilm mit einer ein Silicongel bildenden Masse zusammengebracht wird und die das Silicongel bildende Masse im Kontakt mit dem Siliconelastomerfilm dann unter Bildung eines Schichtstoffs aus einem Silicongel und einem Siliconelastomer gehärtet wird, wobei die Massen zur Bildung des Siliconelastomers und des Silicongels wie im Anspruch 1 definiert sind.

8. Verfahren nach einem der Ansprüche 4 bis 7, dadurch gekennzeichnet, daß der Schichtstoff aus dem Silicongel und dem Siliconelastomer den weiteren Stufen einer Sterilisation und Verpackung unterzogen wird.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